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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,869	12/09/2003	Carl D. Wahlstrand	1023-318US01	6690

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SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,869	WAHLSTRAND ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 33-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31 and 33-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

Applicant's arguments, see page 2, filed May 23, 2006, with respect to the rejection(s) of claim(s) 1-31 and 33-57 under 35 U.S.C. 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kraska et al. (US 4,010,760).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

1. Claims 1-31 and 33-57 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638(US Patent Publication 20040176817 A1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

2. Claims 1-31 and 33-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/730,878 (US Patent Publication 20040176816 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess at least two interconnected modules, each of the modules comprising a housing; and an overmold that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-31 and 33-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,699 (US Patent Publication 20040172090 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess at least two modules, each with a housing and coupling between the modules, wherein the coupling module permits motion of the two modules along at least one axis of motion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-31 and 33-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-54 of

copending Application No. 10/730,873 (US Patent Publication 20040176814 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a plurality of interconnected modules each with a housing and an overmold that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-31 and 33-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/731,867 (US Patent Publication 20040176673 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a plurality of interconnected modules with housings and an a flexible overmold concave along at least one axis that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-31 and 33-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 14-16 of copending Application No. 10/731,868 (US Patent Publication 20040173221 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a first module that includes control electronics within a first housing, a second module that includes a

second housing and a flexible overmold that at least partially covers the first and second housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 12, 21 and 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing claim 12, "device is implanted" to –adapted to be implanted— and claims 21 and 53, "shaped for implantation" to --is adapted to be shaped for implantation--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 recites the limitation "the overmold" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-2, 11-13, 18, 20, 21-23, 35, 37-38, 41-42, 51 and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraska et al. (US 4,010,760). Kraska et al. discloses an implantable medical device as seen in figure 1 with a power supply module 12 of cylindrical shape to fit within the cavity 16 of the signal emitting module 14 which contains the circuitry. The "signal emitting module 14 includes housing 36 containing the electronic circuitry for converting the power supplied by module 12 to a suitable stimulating signal"(col. 2, lines 52-55).

As seen in figure 2, there is an electrically insulating biocompatible resin encapsulation 66 between module 12 and module 14. "An epoxy resin has proved suitable"(col. 3, lines 9-10). Since the epoxy resin fills the cavity, it encapsulates both the interior of module 14 and the exterior of module 12. Furthermore, the examiner considers the epoxy to be flexible.

Furthermore, since module 12 can be rotated within the cavity of module 14 in order to engage module 12 and 14, it follows that the rotation enables the two modules to have a plurality of degrees of freedom.

As to claim 11, since the overmold completely covers the interior cavity 16 of module 14 and the exterior of module 12, the examiner considers the overmold to completely encapsulate the two modules.

As to claim 12, the functional language and introductory statement of intended use of claim 12 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Kraska et al. utilizes medical device with an overmold that does not encapsulate portion of each the first and second module as claimed by the Applicant, Kraska et al. is therefore capable of being positioned so that the unencapsulated portions of the module are implanted proximate to the cranium. In addition nothing prevents Kraska et al. from implanting the unencapsulation portions proximate to the cranium. Therefore, the unencapsulation portion of the medical device is capable of being implanted proximate to the cranium. Furthermore, the claim 12 is vague and appears to be a method claim with the recitation of implantation position.

As to claims 22, 38, 41 and 54, it has been held that the recitation that an element is "capable of" performing a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

As to claims 21 and 53, the functional language and introductory statement of intended use of claims 21 and 53 have been carefully considered but are not

considered to impart any further structural limitations over the prior art. Since Kraska et al. utilizes medical device with an overmold as claimed by the Applicant, Kraska et al. is therefore capable of being shaped for implantation on the cranium. In addition nothing prevents Kraska et al. from being shaped for implantation on the cranium. Therefore, the medical device with an overmold is capable of being shaped for implantation on the cranium.

2. Claims 23-25, 27, 33-34, 37-41 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsukamoto et al. (US Patent Publication 20030085684 A1). Tsukamoto et al. discloses an implantable medical power module incorporating implantable medical device (IMD), which is the first module, implantable power supply or rechargeable battery, which is the second module, and an inductive charging coil, which is the third module.

As depicted in figure 3b, the IMD 248 and implantable power supply 238 are connected by a flexible interconnect member, lead 252, which affords the modules at least three degrees of freedom. Furthermore, since the interconnect member is a lead, it would necessarily be hermetic and have a lumen.

As to claims 38 and 41, it has been held that the recitation that an element is "capable of" performing a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 3-6, 8-11, 13-17, 24-26, 29-31, 42-46, 48-50 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraska et al. (US 4,010,760) in view of Tsukamoto et al (US Patent Publication 20030085684 A1). Kraska et al. discloses the claimed invention except for the rechargeable battery and recharging coil. Tsukamoto et al. teaches that it is known to utilize a rechargeable battery and recharging coil as as set forth in figures 3a and 3b, for the purpose of supplying rechargeable power to the implantable medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the battery as taught by Kraska et al. with the rechargeable battery and recharging coil as taught by Tsukamoto et al., since such a modification would enable the medical device to remain implanted, instead of having to be removed when the power supply is drained. By recharging the

battery, there is no need to explant the medical device to change the batter. As a result, there is no need for invasive surgery to remove the IMD.

As to claims 5-6, 26 and 45-46, Tsukamoto et al. discloses in figures 3a and 3b that the coil can be included with the modules, as seen in figure 3a, or in a third module separate form the other components, as seen in figure 3b.

As to claims 7, 19, 28, 36, 47 and 52, the modified Kraska et al. discloses the claimed invention except for third module being partially encapsulated and the lead connection module being located in the overmold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the location of the third module and the lead connection, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70* (see MPEP 2144.04)

As to claims 8, 29 and 48, the modified Karaska et al. discloses the claimed invention except for the module alignment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the shape or arrangement of the modules, since it has been held that the configuration of the claimed element is a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed element was significant. *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)* See the MPEP 2144.04.

Furthermore, such a modification would enable a reduced size or profile for the implantable medical device for cosmetic or therapeutic reasons. A reduced implant size would make it less noticeable and reduce the necrosis of surrounding tissue.

As to claim 9, the examiner considers the lead 242 in figure 3a to be a flexible tether.

As to claims 10, 31, 50 and 57, the modified Kraska et al. discloses the claimed invention except for the helix tether. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by the modified Kraska et al. with a helix shaped lead since it was known in the art that helix shaped leads reduce the slack in the lead.

As to claims 14-15, the modified Kraska et al. discloses the claimed invention except for silicone overmold or an overmold made of two or more materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the overmold materials or number of materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07)

As to claims 16-17, 30 and 49, Tsukamoto et al. discloses in figures 3b the IMD 248, implantable power supply 238 and the coil 234 as separate modules connected by leads 252 and 242, which the examiner considers to be flexible tethers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alyssa M Alter
Examiner
Art Unit 3762

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
6/9/6